



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Barry Buchbinder, Ph.D., 240-627-3678; [barry.buchbinder@nih.gov](mailto:barry.buchbinder@nih.gov). Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

## **HIV-1 Env Fusion Peptide Immunogens and Their Use**

### **Description of Technology:**

Millions of people are infected with HIV-1 worldwide, and 2.5 to 3 million new infections have been estimated to occur yearly. Although effective antiretroviral therapies are available, millions succumb to AIDS every year, especially in Sub-Saharan Africa, underscoring the need to develop measures to prevent the spread of this disease.

HIV-1 is an enveloped virus, which hides from humoral recognition behind a wide array of protective mechanisms. During infection, the major envelope protein of HIV-1 is cleaved by host cell proteases into two smaller versions (gp120 and gp41). Together gp120 and gp41 make up the HIV-1 Env spike, which is a target for neutralizing antibodies. It is believed that immunization with an effective immunogen based on the HIV-1 Env glycoprotein can elicit a neutralizing response, which may be protective against HIV-1 infection.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases used knowledge from the crystal structure of an HIV-1 neutralizing antibody, VRC34.01, in complex with its epitope on the HIV-1 Env trimer, to develop novel immunogens. HIV-1 uses a fusion peptide, located at the N-terminus of the gp41 subunit, to fuse with a target cell to infect the cell. The crystal structure revealed the epitope recognized by VRC34.01 to be composed primarily of the exposed 8 residues of the fusion peptide at the N-terminus of the gp41 subunit. Researchers designed fusion peptide immunogens that were comprised of the exposed residues of the fusion peptide coupled to highly immunogenic carrier proteins to focus the immune

response to this conserved site of vulnerability. The fusion peptide can be displayed on scaffold proteins and – when coupled to HIV-1 Env trimer boosts – has the potential to elicit antibodies capable of neutralizing diverse HIV-1 strains in mice, guinea pigs and rhesus macaques, and might therefore serve as the basis for an effective HIV vaccine.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

**Potential Commercial Applications:**

HIV-1 vaccine

**Competitive Advantages:**

Potential to be a broadly neutralizing HIV-1 vaccine

**Development Stage:** *In vivo* testing (rodents and non-human primates).

**Inventors:** Peter Kwong (NIAID), John Mascola (NIAID), Kai Xu (NIAID), Rui Kong (NIAID), Tongqing Zhou (NIAID), Li Ou (NIAID), Cheng Cheng (NIAID), Wing-Pui Kong (NIAID), Gwo-Yu Chuang (NIAID), Kevin Liu (NIAID), Michael Gordon Joyce (NIAID), Yongping Yang (NIAID), Baoshan Zhang (NIAID)

**Publications:**

- a) Kong, Rui, et al. "Fusion peptide of HIV-1 as a site of vulnerability to neutralizing antibody." *Science* 352.6287 (2016): 828-833.
- b) Xu, Kai, et al. "Epitope-based vaccine design yields fusion peptide-directed antibodies that neutralize diverse strains of HIV-1." *Nature Medicine* 24, 857-867 (2018).

**Intellectual Property:** HHS Reference Number E-279-2016 includes U.S. Provisional

Patent Application Number 62/403,266 filed 10/03/2016 and PCT Application Number PCT/US2017/054959 filed 10/03/2017 (pending).

**Licensing Contact:** Barry Buchbinder, Ph.D., 240-627-3678; barry.buchbinder@nih.gov

Dated: September 25, 2018.

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Suzanne M. Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018-21762 Filed: 10/5/2018 8:45 am; Publication Date: 10/9/2018]